

## PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E051748-VL	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IT 02/00813	International filing date (day/month/year) 19.12.2002	Priority date (day/month/year) 19.12.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant INVATEC S.r.l. et al.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 2 sheets.

## 3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  22.06.2004	Date of completion of this report  28.04.2005
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Franz, V  Telephone No. +49 89 2399-6084  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IT 02/00813

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-33 as originally filed

**Claims, Numbers**

2-57 as originally filed

1 received on 23.03.2005 with letter of 22.03.2005

**Drawings, Sheets**

1/25-25/25 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	16-19,21,22,30,32-39,42,47-49,54-56
	No: Claims	1-15,20,23-29,31,40,41,43-46,50-53,57
Inventive step (IS)	Yes: Claims	
	No: Claims	1-57
Industrial applicability (IA)	Yes: Claims	1-57
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The present application does not fulfill the requirements of Article 33(3) PCT because the subject-matter of claims **1-15, 20, 23-29, 31, 40, 41, 43-46, 50-53** and **57** is not novel.
  - a. Document US5935162 (**D1**) discloses an expandable endolumenal prosthesis comprising, in the non-expanded configuration, a tubular body (Fig. 1), the tubular body having a porous wall defined by a plurality of interlaced circumferential lines forming a pathway motif or pattern (Fig. 2, item 30), in which at least one line is closed onto itself (Fig. 2; col. 4, lines 41-43), each of the lines extends along an axis (implicit for cylindrical sections as in col. 4, lines 41-43), each of the lines comprises at least one plurality of modules (Fig. 2; col. 4, lines 57-59), each module comprises three lobes, that is, two outer lobes and one inner lobe (*Inner and outer lobes can be defined arbitrarily in the prior art*). Consider the lower left of Fig. 2; going from down to up, three bends define three lobes: The bend open to the left adjacent to the bridge defines an outer lobe, the following bend open to the right defines an inner lobe and the following bend open to the left defines an outer lobe) disposed between the two outer lobes in the pathway of the pattern, each lobe comprising one or more curved sections having concavities facing in the same direction, defining an apex of the lobe (Fig. 2), the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line (col. 5, lines 29-31), both of the outer lobes of the three lobes being extended by straight outer arms (Fig. 2), the at least one plurality of modules being arranged consecutively so as to have successive outer arms which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules (Fig. 2), for each module, the distance between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module (Fig. 2), for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (Fig. 2), at least one connecting element or bridge is provided between two adjacent lines (Fig. 3, item 50), and in which said bridge connects two faced outer lobes of two adjacent lines, said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body (Fig. 2). Therefore, independent claim **1** does not fulfill the requirements of

Article 33(2) PCT.

- b. The same document D1 discloses an expandable endolumenal prosthesis comprising, in the non-expanded configuration: a tubular body extending along a longitudinal axis and having a distal end and a proximal end, the tubular body having a porous wall defined by a plurality of interlaced circumferential pattern lines of which at least one is closed onto itself (Fig. 1), each of the lines extending along an axis (every line extends along an axis), each of the lines comprising at least one series of lobes intercalated by arms, each lobe comprising at least one curved section, each arm constituting a straight section (Fig. 3: the lobes are defined for example between the straight arm 34a and the upper arm of 36a, in the region 36a, between the lower arm 36a and 32a, and the following lobe without reference sign), all of the lobes of the series of lobes opening alternately on opposite sides of the pathway of the pattern, along the extent of the line (for example Fig. 2, column 20a), for every four consecutive lobes separated by three arms, one of the arms having a greater extent than the other two arms (Fig. 2). Therefore, independent claim 57 does not fulfill the requirements of Article 33(2) PCT.
- c. The document D1 also discloses all features of dependent claims **2-15, 20, 23-29, 31, 40, 41, 43-46, and 50-53** (see international search report and references therein). Therefore, independent claim 57 does not fulfill the requirements of Article 33(2) PCT.
2. The present application does not fulfill the requirements of Article 33(3) PCT because the subject-matter of claims **16-19, 21, 22, 30, 32-39, 42, 47-49, 54-56** is not inventive. The additional features are shown in the prior art cited in the international search report and the references cited therein.  
claims **16-18, 30, 35-39, 47-49**: US20020183763 (**D2**)  
claims **19, 21, 22, 32-34**: obvious design option  
claim **42**: US20020065547 (**D3**), Fig. 1: A line forming a pathway motif can be defined by the two points 40 and 15. Its inclination is about 30°.  
claims **54-56**: US6299604 (**D4**): col. 3, lines 6-18
3. The subject-matter as defined by the claims 1-57 of the present invention is suitable for use in industry and moreover it appears to be commercially relevant. Thus, the requirements of Article 33(4) PCT are fulfilled.

**Further remarks**

1. Although claims 1 and 57 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
2. According to the requirements of Rule 11.13(I) reference signs not appearing in the description shall not appear in the drawings, and vice versa. This requirement is not met in view of the reference sign 28 which appears in Figs. 14 and 23 but not in the description.

**CLAIMS**

1. An expandable endolumenal prosthesis comprising, in  
5 the non-expanded configuration,  
- a tubular body extending along a longitudinal axis (1-  
1) and having a distal end and a proximal end,  
- the tubular body having a porous wall defined by a  
plurality of interlaced circumferential lines forming a  
10 pathway motif or pattern, in which:  
- at least one line is closed onto itself,  
- each of the lines extends along an axis (a-a),  
- each of the lines comprises at least one plurality of  
modules,  
15 - each module comprises three lobes, that is, two outer  
lobes and one inner lobe disposed between the two outer  
lobes in the pathway of the pattern,  
- each lobe comprising one or more curved sections having  
concavities facing in the same direction, defining an  
20 apex of the lobe,  
- the lobes opening alternately on opposite sides of the  
pathway of the pattern along the extent of the line,  
- both of the outer lobes of the three lobes being  
extended by straight outer arms,

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- the at least one plurality of modules being arranged consecutively so as to have successive outer arms which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules,
- ~~and in which,~~ for each module, the distance between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module,-
- for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (a-a),
- at least one connecting element or bridge is provided between two adjacent lines,
- and in which said bridge connects two faced outer lobe of two adjacent lines, said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body.